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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 11/14/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/585,821

Applicant(s)

Halvorsen et al.

Examiner

Sandra Saucier

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1651



– Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Aug 30, 2002

2a) ☒ This action is FINAL.

2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 6-15 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 6-15 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7

6) ☐ Other:

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DETAILED ACTION

Claims 6-15 are pending and are considered on the merits.

Claim Rejections – 35 USC § 112

NEW MATTER

Claims 6-15 remain/are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

New claim 6 has inadequate or no support in the as-filed specification and thus is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the new limitations which would show possession of the concept at time of filing.

In the narrative portion of the specification, on page 4, in the "Summary of the Invention" where the broadest statement of the inventors' concept of the invention should be found, the invention is described as "a means to identify novel polypeptides secreted from human adipocytes into the conditioned medium". The medium is described in this paragraph and is stipulated to contain glucose, cyclic AMP inducer, glucocorticoid or analogue thereof, insulin or analogue thereof, and a PPAR or RXR agonist. The methods of the invention as described in the first paragraph also require that at least 25,000 isolated, preadipocyte cells/cm² are plated.

The original claim 6 was also narrower than the instantly claimed method.

Thus, neither the body of the specification nor the original claims supports the newly expanded claim scope.

Further, the claim now requires that "greater than 90%" enriched population of isolated, differentiated, human preadipocytes be obtained prior to identifying a protein or peptide. Please point to the location in the specification where "greater than 90% enriched population" is found.

Please do not broaden the original disclosure by claiming elements not supported at the very least by the broadest statement of invention in the

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specification or an original claim. Applicants are not free to reconstruct and broaden their claimed invention after time of filing.

This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the instant claims are considered to be the insertion of new matter for the above reasons.

Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification.

Please carefully redraft the claimed method in order to avoid further new matter rejections and please point to the specific location in the specification where each of the elements of the claim are found. Assertions of general support are not evidence of support.

Response to Arguments

Applicants argue that the phrase "greater than 90%" does appear in the body of the specification and is, therefore, supported. However, none of the citations made by the applicants to demonstrate support recites the claimed range. Greater than 90% encompasses a range of, for example, 90.1% to 100%. Please note that this range does not include 90%. The term found in the specification at page 4, lines 5-7 "90-95%" is not the same range as expressed by "greater than 90%. The term found in the specification at page 5, line 30 "90-95%" is not the same as the range "greater than 90%". The term "at least 90%" found on page 9, line 1-2, is not the same range as "greater than 90%". Thus, applicants' argument are not well taken and the claimed range has, in fact, expanded the range that is supported by the specification.

Likewise, no support is seen by the examiner for the recitation of "greater than 95%" in new claim 14. No support for this phrase has been cited in the body of the specification by the applicant for this newly introduce claim.

Please note that pending claim 6 still is broader than the broadest statement of invention found in the body of the specification because the claim is

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missing the limitations of the ingredients of the medium and the plating concentration. Applicants may not expand the scope of their invention after filing. Please insert these limitations in accordance with the teachings under "Summary of Invention", where the broadest statement of the invention is found.

INDEFINITE

Claims 6-15 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 now requires that the differentiated cells "exhibit characteristics of an adipocyte". This is unclear because this term does not state how many or what characteristics of an adipocyte are required. For example, must the cell have at least two characteristics in order to fall within this definition as the word, characteristics, is plural? That is, for example, must the cell both secrete leptin and take up Oil Red O? This means that the formation of lipid deposits or oil droplets alone would not be considered sufficient for a cell to be identified as an adipocyte. Use of the phrase "differentiating them into a greater than 90% enriched population of adipocytes" would eliminate this particular rejection and allow greater latitude in the identification of the differentiated cells as well as being definite.

Claim Rejections - 35 USC § 102

Claims 6-8, 11, 13-15 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zilberfarb *et al.* [U].

The claims are directed to a method comprising isolating human preadipocytes, differentiating them into a greater than 90% enriched population having the characteristics of adipocytes and identifying a protein, polypeptide or peptide secreted by the enriched population.

The references are relied upon as explained below.

Zilberfarb *et al.* disclose a method whereby human preadipocytes are differentiated into adipocytes in the presence of medium which contains insulin and pioglitazone (Materials and Methods, page 802). Leptin, a polypeptide, is secreted by the differentiated cells (p. 806). The cells have been genetically modified by introduction of SV 40. Although the % of differentiated cells is not

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directly stated, as the method of differentiating the cells from preadipocytes to adipocytes is the same as the CLAIMED method of differentiating the cells, the result, that is, greater than 90% differentiated cells is reasonably assumed to be the same in the absence of evidence to the contrary. This should be an inherent result of the practice of the same method. The active steps of the method are the same (isolating, differentiating); therefore, the resulting % of differentiation should be the same.

Response to Arguments

Applicant argues that the claimed method isolates preadipocytes from human tissue and then cultures and differentiates them with a minimum of passaging, while the reference used immortalized cells which have been passaged for several months.

While the cells of the reference and the cells of the instantly disclosed method may, in fact be different, the CLAIMED METHOD has no passaging limitation. It is well known that open claim language, e.g., comprising, allows for additional steps to be performed in a method, such as passaging, immortalization etc.. All human cells have been ultimately isolated from human tissue by definition.

Applicants further argue that they culture in fetal calf serum. However, no such limitations are found in the CLAIMED METHOD.

Applicants argue that the method of the reference appears to yield less than 90% differentiated cells. However, arguments of counsel as to appearances are not objective evidence and since the active steps of the CLAIMED METHOD are so broad that they encompass the method of the reference, one may reasonably assume that the same active steps result in the same product. The claimed method recites a desired result without stipulating any specifics which differentiate applicant's disclosed method from the prior art.

Applicant states in the argument that a PPARgamma agonist is essential for differentiation, but then fails to insert this essential ingredient in the claimed method.

The arguments are unpersuasive because the scope of the claims and the scope of the arguments are not commensurate.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00PM Monday, Tuesday and Wednesday 8:30-12:30PM.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
November 12, 2002